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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,919	05/10/2001	Qingsheng Zhu	279.330US1	4736

21186 7590 02/15/2005

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EXAMINER

OROPEZA, FRANCES P

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,919

Applicant(s)

ZHU ET AL. 

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/22/04 (Response).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. Claims 1-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chekanov (US 6201991) and in view of Hauck (US 6560489).

Chekanov discloses a method of prevention and treatment of atherosclerosis in the coronary blood vessels and teaches the use of a pulse generator (25) that includes therapy circuits and a system that includes one or two leads to create non-excitatory electrical field to prevent plaque build-up (col. 2 @ 13-34; col. 3 @ 42-49; col. 9 @ 10-13).

As to claims 3, 8, 13, 14 and 15, Chehonov teaches electrode placement in a single location to create an electric field in the targeted vessel(s) (figure 1; col. 1 @ 46-51; col. 2 @ 17-23 and 36-39), and the use of two lead in the area surrounding the targeted vessel to create a electric field in the targeted vessel(s) (col. 1@ 46-51; col. 2 @ 17-23 col. 3 @ 42-49).

As to claim 11, a electrical pulse generating device is taught using a battery, lead, electronic pulse generating circuitry as exemplified by an implanted pacemaker or cardiomyostimulator, which inherently comprises a hermetically sealed housing to protect the device from damage by body fluids (col. 2 @ 25-30).

Chekanov discloses the claimed invention except:

- delivering sub-stimulation pulses in association with atrial or ventricular depolarization (claims 1, 10, 15, 16),
- using and electrode patch (claims 2 and 12)

- using electrodes on leads in coronary vessels (claims 3, 8, 13, 14, 15) to create the electric fields,
- sensing heart rhythms (claim 4),
- delivering stimulation after the depolarization (during the refractory period) (claim 5, 18, 20),
- providing electrical field spacing about 10 seconds apart (claim 6, 17),
- providing two electrodes on the same lead (claim 7),
- generating the electrical field during a refractory period at a higher strength and generating the electrical field during a non-refractory period at a lower strength (claim 9), and
- a controller and therapy circuit to provide heart rhythm management (claim 19).

Hauck teaches the use of a therapeutic device for treating diseases of the cardiac muscle.

As to delivering sub-threshold depolarization (claims 1, 10, 15, 16), Hauck teaches electrical stimulation using sub-threshold stimulation in association with a ventricular or atrial depolarization for the purpose of producing an electrical field that does not interfere with the heart rhythm. It would have been obvious to one having ordinary skill in the art at the time of the invention to have delivered sub-stimulation pulses in association with atrial or ventricular depolarization in the Chekanov system in order to avoid inducing depolarization of the cardiac tissue, resulting in an unwanted cardiac contraction that induces a life threatening cardiac arrhythmia, placing the patient in grave danger (abstract; col. 1 @ 18-21; col. 3 @ 58 – col. 4 @ 50).

As to an electrode patch (claims 2, 12), Hauck teaches electrical stimulation using an electrode patch for the purpose of producing a targeted electrical field. It would have been obvious to one having ordinary skill in the art at the time of invention to have used an electrode patch in the modified Chekanov system in order to direct the electrical field to the cardiac tissue needing treatment (col. 1 @ 18-21; col. 5 @ 23-26; col. 6 @ 2-4).

As to electrodes on leads (claims 3, 8, 13, 14, 15), Hauck teaches electrical stimulation using lead(s) and electrode combinations implanted in vessels, a single electrode on a lead or an electrode on two different leads, for the purpose of producing a targeted electrical field. It would have been obvious to one having ordinary skill in the art at the time of invention to have use using lead(s) and electrode combinations implanted in vessels, a single electrode on a lead or an electrode on two different leads in the modified Chekanov system in secure the electrode in place so the electrical field is directed to the cardiac tissue needing treatment (figures 3, 4; col. 1 @ 18-21; col. 5 @ 23-26; col. 6 @ 12-20).

As to sensing heart rhythms (claim 4), Hauck teaches therapeutic stimulation using sensing of the cardiac rhythm for the purpose coordinating the timing of the therapeutic stimulation with the sensed heart rhythm. It would have been obvious to one having ordinary skill in the art at the time of the invention to have sensed the heart rhythms in the modified Chekanov system in order to avoid the treatment pulse inducing a life threatening cardiac arrhythmia, placing the patient in grave danger (abstract; col. 3 @ 66 – col. 4 @ 7; col. 4 @ 19-21; col. 5 @ 34-35).

As to generating the electric field after the heart depolarization/ during the refractory period (claims 5, 18, 20), Hauck teaches electrical stimulation using therapeutic stimulation after

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the heart depolarization/ during the refractory period for the purpose of producing an electrical field that does not adversely impact the heart rhythm. It would have been obvious to one having ordinary skill in the art at the time of the invention to have delivered the field after the heart depolarization/ during a refractory period in the modified Chekanov system in order to avoid inducing depolarization of the cardiac tissue, resulting in an unwanted cardiac contraction that induces a life threatening cardiac arrhythmia, placing the patient in grave danger (abstract; col. 1 @ 18-21; col. 3 @ 58 – col. 4 @ 50; col. 4 @ 26-29 and 43-50).

As to providing the stimulation about 10 seconds apart (claims 6, 17), Hauck teaches electrical stimulation using stimulation frequency in the range of two fields per second to two hundred fields per second and teaches the significant variability of therapeutic pulse requirement of different patients (col. 6 @ 54-57; col. 3 @ 60-64). The instant invention teaches field spacing between once every minute to two fields every three seconds (specification – page 7, line 20-24), hence teaching significant variation in the timing of the electric field. These disclosures provide a clear suggestion that the timing of the electric fields can be modified according to patient needs to optimize the impact of the electrical field on the patient's condition. The determination of the most appropriate timing of the electrical field by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the cardiac tissue stimulation art. It would have been obvious to one having ordinary skill in the art at the time of invention to have used experimentation to determine the optimum timing for the electrical field generation in the modified Chekanov system in order to effectively and efficiently treat the cardiac tissue (col. 1 @ 18-21).

As to providing two electrodes (claim 7), Hauck teaches cardiac treatment using two electrodes on the same lead for the purpose of directing the treatment field to the region where the treatment is required. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used two electrodes on the same lead in the modified Chekanov system in order to avoid energy loss caused by lack of proper targeting of the sub-threshold stimulation pulses (col. 1 @ 18-21; col. 6 @ 28-36).

As to claim 9, Hauck teaches cardiac treatment using subthreshold electrical current to generate an electrical field during a cardiac cycle, the stimulation during a refractory period at a higher strength and generate the electrical field during a non-refractory period at a lower strength (col. 4 @ 19-37) for the purpose of providing therapeutic subthreshold electrical fields. It would have been obvious to one having ordinary skill in the art at the time of the invention to have generated an electrical field during a refractory period at a higher strength and generate the electrical field during a non-refractory period at a lower strength in the modified Chekanov system in order to avoid the treatment pulse inducing a life threatening cardiac arrhythmia, placing the patient in grave danger (abstract; col. 1 @ 18-21; col. 3 @ 58 – col. 4 @ 61; col. 4 @ 43-50).

As to a controller and therapy circuits (claim 19), Hauck teaches cardiac treatment using a controller and therapy circuits as an integral part of the therapy device for the purpose treating arrhythmias of the heart. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a controller and therapy circuits in the modified Chekanov system in order to provide treatment for the potentially life arrhythmic conditions present in many cardiac patients with compromised cardiac systems (col. 1 @ 18-21; col. 4 @ 37-38).

The Applicant's arguments filed 11/22/04 have been fully considered but they are not convincing.

The Applicant argues motivation to combine the Chekanov and Hauck references is lacking.

In his first argument, the Applicant appears to assert the references are not combinable because Hauck focuses on stimulating the heart and Chekanov teaches away from "non-muscle-stimulating electrical energy" because Chekanov uses his device to stimulate muscle contractions. The Examiner disagrees. Hauck teaches stimulating the heart. Chekanov teaches stimulating muscle, including the heart muscle, as the Chekanov device is used for treatment of the coronary vessels, or vessels of the heart, hence stimulating the heart muscle to create the therapeutic electric field for the coronary vessels (col. 2 @ 6-16).

In his second argument, the Applicant asserts the references are not combinable because Chekanov teaches using stimulating current to prevent or decrease plaque in blood vessels, and Hauck teaches the loss of blood flow, possibly resulting from arteriosclerosis (associated with plaque), is treated by promoting angiogenesis with stimulating current to remodel the cardiac tissue. The Applicant appears to assert Hauck teaches preclude stimulation treatment to treat arteriosclerosis/ plaque, but in review of the cited passage, the Examiner finds this is not the case (col. 2 @ 30-56). The treatments taught by Hauck and Chekanov both provide stimulating current to the heart and both treatments require care when stimulating cardiac tissue so there is not interference with the heart rhythm, especially during periods when the heart is not depolarized.

In his third argument, the Applicant asserts the references are not combinable because Hauck teaches treating heart tissue and Chekanov teaches treating blood vessels. The Examiner disagrees. Hauck teaches stimulating the heart tissue and Chekanov teaches stimulating muscle, including the heart muscle, as the Chekanov device is used for treatment of the coronary vessels/ heart vessels, therefore stimulating the heart tissue (col. 2 @ 6-6)

Based on the rejection of record and the discussion in the three previous paragraphs, the references are deemed combinable.

The Applicant asserts the proposed modifications would render references unsatisfactory for their intended purpose because Hauck seeks to prevent the level of current from inducing unwanted heart depolarizations and Chekanov teaches stimulating muscle contractions. The Examiner disagrees. Both references teach the creation of an electric field and not necessarily a contraction (Hauck - abstract; Chekanov – col. 1 @ 46-51), hence the references would not be rendered unsatisfactory for their intended purpose.

Relative to claims 2 and 12, the Applicant asserts the references do not teach an epicardial electrode patch. The Examiner disagrees. Hauck teaches an epicardial electrode patch (electrode on the heart – col. 5 @ 23-26; the electrode being a patch – col. 8 @ 16).

Relative to claims 6 and 17, the Applicant asserts the references do not teach electrical fields spaced about ten seconds apart. The Examiner disagrees. As noted above in the rejection of record: Hauck teaches electrical stimulation using stimulation frequency in the range of two fields per second to two hundred fields per second and teaches the significant variability of therapeutic pulse requirement of different patients (col. 6 @ 54-57; col. 3 @ 60-64). The instant invention teaches field spacing between once every minute to two fields every three seconds

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(specification – page 7, line 20-24), hence teaching significant variation in the timing of the electric field. These disclosures provide a clear suggestion that the timing of the electric fields can be modified according to patient needs to optimize the impact of the electrical field on the patient's condition. The determination of the most appropriate timing of the electrical field by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the cardiac tissue stimulation art. It would have been obvious to one having ordinary skill in the art at the time of invention to have used experimentation to determine the optimum timing for the electrical field generation in the modified Chekanov system in order to effectively and efficiently treat the cardiac tissue (col. 1 @ 18-21).

Relative to claims 8, 14 and 15, the Applicant asserts the references do not teach two leads, each with an electrode, and spacing the electrodes apart to reduce plaque in the coronary artery. The Examiner disagrees. Chekanov teaches the use of an electrode on a lead (figure 1 – 22) and two leads (col. 3 @ 45) spaced to create an electric field to reduce plaque (col. 1 @ 46-51) in the coronary artery (col. 2 @ 15).

Relative to claim 15, the Applicant asserts the references do not teach two leads adapted to be positioned in the anterior vein and the lateral vein, the electrical field passing through the left marginal artery and the anterior interventricular artery. The Examiner disagrees. Hauck teaches the electrodes are adapted to be implanted in the cardiac vessels (col. 5 @ 25), inherently including the anterior vein and the lateral vein, and based on placement creating an electrical field passing through the left marginal artery and the anterior interventricular artery.

Statutory Basis

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

THIS ACTION IS MADE FINAL. The Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

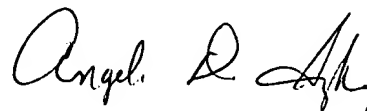
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5:30 p.m..

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular and for After Final communications.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO 2/5/05



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